

K021150 COULTER CELLPREPJun 11, 2002
62 days to decisionK021150 · Product code: **GKH** · Hematology
Source: <https://www.510kdatabase.net/k021150/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Automated Blood Cell Diluting (GKH)
Date received	Apr 10, 2002
Decision date	Jun 11, 2002
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	LOURDES COBA
Website	https://www.beckmancoulter.com
510(k) history	270 submissions · 270 cleared · 1993-2026

Beckman Coulter, Inc. is a diagnostic device manufacturer headquartered in Chaska, US. The company specializes in clinical laboratory and immunodiagnostic systems. Beckman Coulter has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with the latest clearance in 2026. Its portfolio spans chemistry devices, microbiology testing systems, hematology analyzers, and immunoassay platforms. Recent cleared devices include chemistry assays for cardiac markers, microbiology susceptibility panels,...

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Device record: <https://www.510kdatabase.net/k021150/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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